NIDA Clinical Trials Network

Adverse Events (AD1)

Web Version: 1.0; 4.00; 10-02-15

Adverse event onset date *(AEDATE)*:
Event number *(AESEQNUM)*:

This adverse event has been closed by the Medical Reviewer and may no longer be updated.

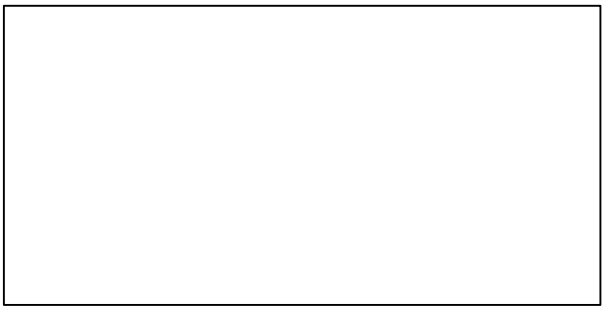
For the purposes of this protocol, Grade 1 (mild) unrelated adverse events should not be reported in AdvantageEDC.

1. Adverse event name: *(A1DESCPT)*
2. Date site became aware of the event: *(A1AWARDT)* *(mm/dd/yyyy)*
3. Severity of event: *(A1SEVRTY)*
4. Is there a reasonable possibility that the study drug caused the event? *(A1RDRUG1)* ☐ No ☐ Yes
   If "Yes", action taken with the study drug: *(A1ADRUG1)*
5. If "Unrelated" to the study drug, alternative etiology: *(A1ALTESD)*
   If "Other," specify: *(A1AEPSP)*
6. Outcome of event: *(A1OUTCM)*
7. Date of resolution or medically stable: *(A1RESDT)* *(mm/dd/yyyy)*

Except for "None of the following", all selections in the question below will designate this as a Serious Adverse Event (SAE). The Serious Adverse Event Summary (AD2) form should be completed for all Serious Adverse Events reported.

8. Was this event associated with: *(A1ASSOC)*
   a. If "Death", date of death: *(A1DTHDT)* *(mm/dd/yyyy)*
   b. If "Inpatient admission to hospital or prolongation of hospitalization":
      Date of hospital admission: *(A1HOSPAD)* *(mm/dd/yyyy)*
      Date of hospital discharge: *(A1HOSPDC)* *(mm/dd/yyyy)*

Comments:*(AD1COMM)*



Additional Selection Options for AD1

Event number *(AESEQNUM)* (key field):
01-1st Adverse Event of the day
02-2nd Adverse Event of the day
03-3rd Adverse Event of the day
04-4th Adverse Event of the day
05-5th Adverse Event of the day
06-6th Adverse Event of the day
07-7th Adverse Event of the day
08-8th Adverse Event of the day
09-9th Adverse Event of the day
10-10th Adverse Event of the day

Was this event associated with:
5-Congenital anomaly or birth defect
6-Important medical event that required intervention to prevent any of the above
7-Seizure
8-Hospitalization for a medical event

NIDA Clinical Trials Network

Serious Adverse Event Summary (AD2)

Web Version: 1.0; 1.00; 02-25-15

Adverse event onset date *(AEDATE)*:
Event number *(AESEQNUM)*:

This adverse event has been closed by the Medical Reviewer and may no longer be updated.

1. Initial narrative description of serious adverse event:

(A2SUMM)

2. Relevant past medical history: *(A2SAEMHX)* ☐ No ☐ Yes ☐ Unknown
Allergies, pregnancy, smoking and alcohol use, hypertension, diabetes, epilepsy, depression, etc.

(A2MEDHX)

3. Medications at the time of the event: *(A2SAEMED)* ☐ No ☐ Yes ☐ Unknown

Medication (Generic Name)	**Indication**
(A2_01DNM)	*(A2_01DIN)*
(A2_02DNM)	*(A2_02DIN)*
(A2_03DNM)	*(A2_03DIN)*
(A2_04DNM)	*(A2_04DIN)*
(A2_05DNM)	*(A2_05DIN)*
(A2_06DNM)	*(A2_06DIN)*
(A2_07DNM)	*(A2_07DIN)*
(A2_08DNM)	*(A2_08DIN)*
(A2_09DNM)	*(A2_09DIN)*
(A2_10DNM)	*(A2_10DIN)*

4. Treatments for the event: *(A2SAETRT)* ☐ No ☐ Yes ☐ Unknown

Treatment	**Indication**	**Date Treated** *(mm/dd/yyyy)*
(A2_1TNME)	*(A2_1TIND)*	*(A2_1LTDT)*

(A2_2TNME)	*(A2_2TIND)*	*(A2_2LTDT)*
(A2_3TNME)	*(A2_3TIND)*	*(A2_3LTDT)*
(A2_4TNME)	*(A2_4TIND)*	*(A2_4LTDT)*
(A2_5TNME)	*(A2_5TIND)*	*(A2_5LTDT)*

5. Labs/tests performed in conjunction with this event: *(A2SAELAB)* ☐ No ☐ Yes ☐ Unknown

Lab/Test	**Findings**	**Date of Test** *(mm/dd/yyyy)*
(A2_1LBNM)	*(A2_1LBIN)*	*(A2_1LBDT)*
(A2_2LBNM)	*(A2_2LBIN)*	*(A2_2LBDT)*
(A2_3LBNM)	*(A2_3LBIN)*	*(A2_3LBDT)*
(A2_4LBNM)	*(A2_4LBIN)*	*(A2_4LBDT)*
(A2_5LBNM)	*(A2_5LBIN)*	*(A2_5LBDT)*

6. Follow-up:

Include labs/test results as they become available, clinical changes, consultant diagnosis, etc.

(A2FOLLUP)

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7. Additional information requested by the Medical Monitor:

(A2ADDINF)

Have all Medical Monitor requests been addressed?*(A2RQADDR)* ☐ Yes

Additional Selection Options for AD2

Event number *(AESEQNUM)* (key field):
01-1st Adverse Event of the day
02-2nd Adverse Event of the day
03-3rd Adverse Event of the day
04-4th Adverse Event of the day
05-5th Adverse Event of the day
06-6th Adverse Event of the day
07-7th Adverse Event of the day
08-8th Adverse Event of the day
09-9th Adverse Event of the day
10-10th Adverse Event of the day

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Serious Adverse Event Medical Reviewer (AD3)

Web Version: 1.0; 3.00; 08-19-14

Adverse event onset date *(AEDATE)*:
Event number *(AESEQNUM)*:

1. Was this determined to be a serious adverse event?*(A3SAE)*	☐ No ☐ Yes
2. Was this event considered associated with the study drug?*(A3RELDRG)*	☐ No ☐ Yes
3. Was this event expected?*(A3EXPECT)*	☐ No ☐ Yes
4. Is this a standard expedited/reportable event? *(i.e., is it serious, unexpected and related to therapy)(A3EXPFDA)*	☐ No ☐ Yes
If "No", is this an expedited/reportable event for other reasons?*(A3EXPOTH)*	☐ No ☐ Yes
5. Does the protocol need to be modified based on this event?*(A3MPROT)*	☐ No ☐ Yes
6. Does the consent form need to be modified based on this event?*(A3MCNST)*	☐ No ☐ Yes
7. Is the review complete?*(A3REVDNE)*	☐ No ☐ Yes
If "No", what additional information is required:*(A3ADDINF)*	

Assessed by:*(A3ASRID)* ☐ (intials)

Reviewed by:*(A3REVID)* ☐ (intials)

Comments:*(A3COMM)*

Additional Selection Options for AD3

Event number *(AESEQNUM)* (key field):
01-1st Adverse Event of the day
02-2nd Adverse Event of the day
03-3rd Adverse Event of the day
04-4th Adverse Event of the day
05-5th Adverse Event of the day
06-6th Adverse Event of the day
07-7th Adverse Event of the day
08-8th Adverse Event of the day
09-9th Adverse Event of the day
10-10th Adverse Event of the day

NIDA Clinical Trials Network

Alcohol and Substance Use History (ASU)

Web Version: 1.0; 2.00; 11-26-13

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment:*(ASUASMDT)* _____ *(mm/dd/yyyy)*

Alcohol Use History

1. In your entire life, have you had at least 1 drink of any kind of alcohol, not counting small tastes or sips?*(AUALCLFT)* ☐ No ☐ Yes
   If "Yes", about how old were you when you first started drinking, not counting small tastes or sips of alcohol?*(AUALCAGE)* _____ *(xx)*

Substance Use History

Substance	Have you EVER used any of these medicines or drugs?	If "Yes", specify:	How old were you when you FIRST used? *(age in years)*
2. Sedatives: (e.g., sleeping pills, barbiturates, Seconal, Quaaludes, or Chloral Hydrate)	*(AUSEDLFT)* ☐ No ☐ Yes	*(AUSEDLSP)*	*(AUSEDAGE)* *(xx)* years
3. Tranquilizers: or anti-anxiety drugs: (e.g., Valium, Librium, muscle relaxants, or Xanax)	*(AUTNQLFT)* ☐ No ☐ Yes	*(AUTNQLSP)*	*(AUTRQAGE)* *(xx)* years
4. Painkillers: (e.g., Codeine, Darvon, Percodan, Oxycontin, Dilaudid, or Demerol)	*(AUPNKLFT)* ☐ No ☐ Yes	*(AUPNKLSP)*	*(AUPNKAGE)* *(xx)* years
5. Stimulants: (e.g., Preludin, Benzedrine, Methedrine, Ritalin, uppers, or speed)	*(AUSTMLFT)* ☐ No ☐ Yes	*(AUSTMLSP)*	*(AUSTMAGE)* *(xx)* years
6. Marijuana, hash, THC, grass, or cannabis:	*(AUTHCLFT)* ☐ No ☐ Yes	*(AUTHCLSP)*	*(AUTHCAGE)* *(xx)* years
7. Cocaine or crack:	*(AUCOCLFT)* ☐ No ☐ Yes	*(AUCOCLSP)*	*(AUCOCAGE)* *(xx)* years
8. Hallucinogens: (e.g., Ecstasy, MDMA, LSD, Mescaline, psilocybin, PCP, angel dust, or peyote)	*(AUHALLFT)* ☐ No ☐ Yes	*(AUHALLSP)*	*(AUHALAGE)* *(xx)* years
9. Inhalants or solvents: (e.g., amyl nitrite, nitrous oxide, glue, toluene, or gasoline)	*(AUINHLFT)* ☐ No ☐ Yes	*(AUINHLSP)*	*(AUINHAGE)* *(xx)* years
10. Heroin:	*(AUHERLFT)* ☐ No ☐ Yes		*(AUHERAGE)* *(xx)* years
11. Any OTHER medicines, drugs, or substances: (e.g., methadone, Elavil, steroids, Thorazine, or Haldol)	*(AUOTHLFT)* ☐ No ☐ Yes	*(AUOTHLSP)*	*(AUOTHAGE)* *(xx)* years

Comments:*(ASUCOMM)*

NIDA Clinical Trials Network

Concise Health Risk Tracking (CHRT) - Clinician Rated Module (CHC)

Web Version: 1.0; 1.00; 01-16-14

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment:*(CHCASMDT)* _____ *(mm/dd/yyyy)*

1. **Suicidal Ideation** - Passive (i.e. wanting to be dead) and/or active (i.e. method, intent, plan) SI present.*(CHSCIDTN)* ☐ No ☐ Yes
   This last week did you think you might be better off dead or wish you were dead?
   Did you have any thoughts of harming or injuring yourself in any way?
   If "Yes": **Have you thought about how you might do this?**
   Have there been times when you seriously considered harming or injuring yourself?
   Do you intend to kill yourself or harm yourself in any way? Do you have a plan?
   How often have you had these thoughts? How long do they last?

2. **Suicide Attempt** - Patient made a suicide attempt (i.e. they engaged in a potentially self-injurious behavior associated with intent to die. Intent can be stated by patient or inferred by rater).*(CHSCATMP)* ☐ No ☐ Yes
   This last week did you attempt to harm or injure yourself in any way?
   If "Yes": **Can you tell me what happened? Was this an accident or on purpose?**
   If On Purpose: **Why did you _____? Were you trying to kill yourself when you _____?**
   If **"Yes"**, list method: *(CHMETHOD)* _____

3. **Self-injurious Behavior - No Intent to Die** - Purposeful self-injurious behavior with no intent to die.*(CHSIBDIE)* ☐ No ☐ Yes
   This last week, have you done anything to prepare yourself for suicide or take any steps towards killing yourself?
   If "Yes": **What did you do? Were you thinking about killing yourself when you _____?**
   Did you stop yourself, or did someone else stop you before you harmed yourself?

4. **Preparatory Acts** - Making preparatory acts toward imminent suicidal behavior (Person takes steps to injure self but is stopped by self or others. Intent to die is either stated by patient or inferred by rater).*(CHPREPAT)* ☐ No ☐ Yes

5. **Completed Suicide** - Confirmed (i.e. Coroner's report, suicide note, other collateral information).*(CHSCCMPL)* ☐ No ☐ Yes

6. **Self-injurious Behavior - Unknown Intent**- Purposeful self-injurious behavior where associated intent to die is unknown and cannot be inferred.*(CHSIBUNK)* ☐ No ☐ Yes

7. **Death (not enough information to classify as suicide)***(CHDEATH)* ☐ No ☐ Yes

8. **Other Injury -** Other not purposeful injury (accidental, psychiatric, medical), no deliberate self-harm.*(CHINJOTH)* ☐ No ☐ Yes

9. **Nonfatal Injury (not enough information to classify)** *(CHINJURY)* ☐ No ☐ Yes

Comments:*(CHCCOMM)*

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Concise Health Risk Tracking (CHRT) - Participant Rated Module (CHP)

Web Version: 1.0; 1.02; 04-09-14

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment:*(CHPASMDT)* _____ *(mm/dd/yyyy)*

Please rate the extent to which each of the following statements describes how you have been feeling or acting in the past week.
For example, if you feel the statement very accurately describes how you have been feeling in the past week, you would give a rating of "Strongly Agree." If you feel the statement is not at all how you have been feeling in the past week, you would give a rating of "Strongly Disagree."

		Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
1. I feel as if things are never going to get better.	*(CHNVRBTR)*	☐	☐	☐	☐	☐
2. I have no future.	*(CHNOFUTR)*	☐	☐	☐	☐	☐
3. It seems as if I can do nothing right.	*(CHNORGHT)*	☐	☐	☐	☐	☐
4. Everything I do turns out wrong.	*(CHWRONG)*	☐	☐	☐	☐	☐
5. There is no one I can depend on.	*(CHDEPEND)*	☐	☐	☐	☐	☐
6. The people I care the most for are gone.	*(CHPPLGNE)*	☐	☐	☐	☐	☐
7. I wish my suffering could just all be over.	*(CHSUFFER)*	☐	☐	☐	☐	☐
8. I feel that there is no reason to live.	*(CHRSLIVE)*	☐	☐	☐	☐	☐
9. I wish I could just go to sleep and not wake up.	*(CHSLEEP)*	☐	☐	☐	☐	☐
10. I find myself saying or doing things without thinking.	*(CHNOTHNK)*	☐	☐	☐	☐	☐
11. I often make decisions quickly or "on impulse."	*(CHIMPULS)*	☐	☐	☐	☐	☐
12. I often feel irritable or easily angered.	*(CHIRRITE)*	☐	☐	☐	☐	☐
13. I often overreact with anger or rage over minor things.	*(CHOVRRCT)*	☐	☐	☐	☐	☐
14. I have been having thoughts of killing myself.	*(CHKILLMS)*	☐	☐	☐	☐	☐
15. I have thoughts about how I might kill myself.	*(CHHOWKIL)*	☐	☐	☐	☐	☐
16. I have a plan to kill myself.	*(CHPLNKIL)*	☐	☐	☐	☐	☐

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Cannabis Use Quantification (CUQ)

Web Version: 1.0; 1.00; 10-21-13

Date of assessment: *(mm/dd/yyyy)*	In the past 30 days, have you used any of these methods to administer cannabis?	If "Ingestion" or "Other", specify:	On average, how much cannabis do you use? *(xx.xx grams)*	What would be the estimated dollar value for this amount of cannabis? *($xxx)*
1. *(CUAS01DT)*	*(CUMETH01)*	*(CUMESP01)*	*(CUAMT1)*	*(CUSPNT01)*
2. *(CUAS02DT)*	*(CUMETH02)*	*(CUMESP02)*	*(CUAMT2)*	*(CUSPNT02)*
3. *(CUAS03DT)*	*(CUMETH03)*	*(CUMESP03)*	*(CUAMT3)*	*(CUSPNT03)*
4. *(CUAS04DT)*	*(CUMETH04)*	*(CUMESP04)*	*(CUAMT4)*	*(CUSPNT04)*
5. *(CUAS05DT)*	*(CUMETH05)*	*(CUMESP05)*	*(CUAMT5)*	*(CUSPNT05)*
6. *(CUAS06DT)*	*(CUMETH06)*	*(CUMESP06)*	*(CUAMT6)*	*(CUSPNT06)*
7. *(CUAS07DT)*	*(CUMETH07)*	*(CUMESP07)*	*(CUAMT7)*	*(CUSPNT07)*

	1-Joints 2-Blunts 3-Pipe/Bowl 4-Bong 5-Ingestion *Additional Options Listed Below			
8. *(CUAS08DT)*	*(CUMETH08)*	*(CUMESP08)*	*(CUAMT8)*	*(CUSPNT08)*

Comment *(CUQCOMM)*

Additional Selection Options for CUQ

Method 1
6-Vaporizers
98-Other 1
99-Other 2

NIDA Clinical Trials Network

Cannabis Withdrawal Scale (CWS)

Web Version: 1.0; 1.01; 03-20-14

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment:*(CWSASMDT)* _____ *(mm/dd/yyyy)*

*The following statements describe how you have felt over the **last 24 hours**. Please check the box that most closely represents your personal experiences for each statement. For each statement, please rate its **negative** impact on normal daily activities on the same scale (0 = Not at all to 10 = Extremely), indicating the number in the right hand column.*

	Not at All 0	1	2	3	4	5	6	7	8	9	Extremely 10	Negative Impact on Daily Activity (0-10)
1. The only thing I could think about was smoking some cannabis:	*(CWSMOKE)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWSMOKEN)* ____ *(xx)*
2. I had a headache:	*(CWHEAD)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWHEADN)* ____ *(xx)*
3. I had no appetite:	*(CWAPPET)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWAPPETN)* ____ *(xx)*
4. I felt nauseous (like vomiting):	*(CWVOMIT)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWVOMITN)* ____ *(xx)*
5. I felt nervous:	*(CWNERVE)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWNERVEN)* ____ *(xx)*
6. I had some angry outbursts:	*(CWANGRY)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWANGRYN)* ____ *(xx)*
7. I had mood swings:	*(CWMOOD)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWMOODN)* ____ *(xx)*
8. I felt depressed:	*(CWDEPRES)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWDEPREN)* ____ *(xx)*
9. I was easily irritated:	*(CWIRRITA)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWIRRITN)* ____ *(xx)*
10. I had been imagining being stoned:	*(CWSTONE)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWSTONEN)* ____ *(xx)*
11. I felt restless:	*(CWREST)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWRESTN)* ____ *(xx)*
12. I woke up early:	*(CWWOKEUP)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWWOKEN)* ____ *(xx)*
13. I had a stomach ache:	*(CWACHE)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWACHEN)* ____ *(xx)*
14. I had nightmares and/or strange dreams:	*(CWDREAM)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWDREAMN)* ____ *(xx)*
15. Life seemed like an uphill struggle:	*(CWUPHILL)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWUPHLLN)* ____ *(xx)*
16. I woke up sweating at night:	*(CWSWEAT)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWSWEATN)* ____ *(xx)*
17. I had trouble getting to sleep at night:	*(CWINSOMN)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWINSONN)* ____ *(xx)*
18. I felt physically tense:	*(CWTENSE)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWTENSEN)* ____ *(xx)*
19. I had hot flashes:	*(CWFLASH)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	*(CWFLASHN)* ____ *(xx)*

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Demographics (DEM)

Web Version: 1.0; 2.02; 07-11-14

1. Date of birth:*(DEBRTHDT)* _____ *(mm/dd/yyyy)*

3. Gender:*(DEGENDER)* ☐ Male ☐ Female ☐ Don't know ☐ Refused

4. Does the participant consider him or herself to be Hispanic/Latino?*(DEHISPNC)* ☐ No ☐ Yes ☐ Don't know ☐ Refused

   If "Yes", indicate the group that represents his or her Hispanic origin or ancestry:*(DEHISPSP)*

5. What race does the participant consider him or herself to represent:
   (Check all that apply)

White:	*(DEWHITE)* ☐		
Black/ African American:	*(DEBLACK)* ☐		
Indian (American):	*(DEAMEIND)* ☐		
Alaska native:	*(DEALASKA)* ☐		
Native Hawaiian:	*(DEHAWAII)* ☐		
Guamanian:	*(DEGUAM)* ☐		
Samoan:	*(DESAMOAN)* ☐		
Other Pacific Islander:	*(DEPACISL)* ☐	Specify:*(DEPACISO)*	
Asian Indian:	*(DEASAIND)* ☐		
Chinese:	*(DECHINA)* ☐		
Filipino:	*(DEFILIPN)* ☐		
Japanese:	*(DEJAPAN)* ☐		
Korean:	*(DEKOREA)* ☐		
Vietnamese:	*(DEVIETNM)* ☐		
Other Asian:	*(DEASIAN)* ☐	Specify:*(DEASIAOT)*	
Some other race:	*(DERACEOT)* ☐	Specify:*(DERACESP)*	

-OR- ---

Don't know:*(DERACEDK)* ☐

Refused: *(DERACERF)* ☐

6. What is the highest grade or level of school the participant has completed or the highest degree they have received?*(DEEDUCTN)*

7. We would like to know about what the participant does -- is he/she working now, looking for work, retired, keeping house, a student, or what?*(DEJOB)*

If "Other", specify:*(DEJOBSP)*

8. Is the participant married, widowed, divorced, separated, never married, or living with a partner?*(DEMARTL)*

Comments:*(DEMCOMM)*

Additional Selection Options for DEM

If "Yes", indicate the group that represents his or her Hispanic origin or ancestry:
6-Cuban
7-Cuban American
8-Central or South American
9-Other Latin American
99-Other Hispanic
98-Refused
97-Don't know

What is the highest grade or level of school the participant has completed or the highest degree they have received?
05-5th grade
06-6th grade
07-7th grade
08-8th grade
09-9th grade
10-10th grade
11-11th grade
12-12th grade, no diploma
13-High school graduate
14-GED or equivalent
15-Some college, no degree
16-Associate's degree: occupational, technical, or vocational program
17-Associate's degree: academic program
18-Bachelor's degree (e.g., BA, AB, BS, BBA)
19-Master's degree (e.g., MA, MS, MEng, MEd, MBA)
20-Professional school degree (e.g., MD, DDS, DVM, JD)
21-Doctoral degree (e.g., PhD, EdD)
98-Refused
97-Don't know

We would like to know about what the participant does -- is he/she working now, looking for work, retired, keeping house, a student, or what?
06-Keeping house
07-Student
99-Other

Is the participant married, widowed, divorced, separated, never married, or living with a partner?
06-Living with partner
98-Refused
99-Don't know

NIDA Clinical Trials Network

DSM-IV - Substance Related Disorders (DSD)

Web Version: 1.0; 2.00; 02-11-14

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment:*(DSDASMDT)* _____ *(mm/dd/yyyy)*

1. Have you used _____ in the past 12 months? (Continue the assessment only for drugs used within the past 12 months.)

Marijuana	Alcohol	Cocaine	Amphetamines	Opioids	Benzodiazepines	Other
(DSUSMJNA)	*(DSUSALCH)*	*(DSUSCOCN)*	*(DSUSAMP)*	*(DSUSOPIA)*	*(DSUSBENZ)*	*(DSUSOTHR)*

Substance DEPENDENCE Criteria

A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by **three** (or more) of the following, occurring at any time within the same 12-month period.

A1 Have you found that you needed to use a lot more (drug) in order to get high than you did when you first started using it? IF YES: How much more? IF NO: What about finding that when you used the same amount, it had much less effect than before? *Tolerance, as defined by either a need for markedly increased amounts of the substance in order to achieve intoxication or desired effect, or markedly diminished effect with continued use of the same amount of substance.*

Marijuana	Alcohol	Cocaine	Amphetamines	Opioids	Benzodiazepines	Other
(DSNDMJNA)	*(DSNDALCH)*	*(DSNDCOCA)*	*(DSNDAMPH)*	*(DSNDOPIA)*	*(DSNDBENZ)*	*(DSNDOTHR)*

Present for marijuana in the last 30 days?*(DSNDMJ30)* ☐ No ☐ Yes

A2 Have you ever had withdrawal symptoms, that is felt sick when you cut down or stopped using (drug)? IF YES: What symptom have you had? *(Need to refer to withdrawal symptoms associated with each drug.)* Have you used (drug) to keep yourself from getting sick with (specific withdrawal symptom[s])? *Withdrawal, as manifested by either the characteristic withdrawal syndrome for the substance (see special criteria sets for withdrawal in p. 185 of DSM-IV manual) or the same (or closely related) substance is taken to relieve or avoid withdrawal symptoms.*

Marijuana	Alcohol	Cocaine	Amphetamines	Opioids	Benzodiazepines	Other
(DSWDMJNA)	*(DSWDALCH)*	*(DSWDCOCA)*	*(DSWDAMPH)*	*(DSWDOPIA)*	*(DSWDBENZ)*	*(DSWDOTHR)*

Present for marijuana in the last 30 days?*(DSWDMJ30)* ☐ No ☐ Yes

A3 Have you often found that when you started using (drug), you ended up using more of it than you were planning to? IF NO: What about using it over a much longer period of time than you were planning to? *Substance often taken in larger amounts or over a longer period than subject intended.*

Marijuana	Alcohol	Cocaine	Amphetamines	Opioids	Benzodiazepines	Other
(DSSDMJNA)	*(DSSDALCH)*	*(DSSDCOCA)*	*(DSSDAMPH)*	*(DSSDOPIA)*	*(DSSDBENZ)*	*(DSSDOTHR)*

Present for marijuana in the last 30 days?*(DSSDMJ30)* ☐ No ☐ Yes

A4 Have you tried to cut down or stop using (drug)? IF YES: Have you ever actually stopped using (drug) altogether? (How many times did you try to cut down or stop altogether?) IF UNCLEAR: Did you want to stop or cut down? IF NO: Is this something you kept worrying about? *Persistent desire or one or more unsuccessful efforts to cut down or control substance use.*

Marijuana	Alcohol	Cocaine	Amphetamines	Opioids	Benzodiazepines	Other
(DSCTMJNA)	*(DSCTALCH)*	*(DSCTCOCA)*	*(DSCTAMPH)*	*(DSCTOPIA)*	*(DSCTBEZO)*	*(DSCTBENZ)*

0-Present 1-Absent 2-Uncertain						

Present for marijuana in the last 30 days?*(DSCTMJ30)* ☐ No ☐ Yes

A5 Have you spent a lot of time using (drug) or doing whatever you had to do to get it? Did it take you a long time to get back to normal? (How much time?) *A great deal of time spent in activities necessary to get the substance (e.g., visiting multiple doctors or driving long distances), use the substance (e.g., chain smoking) or recover from its effects.*

Marijuana	Alcohol	Cocaine	Amphetamines	Opioids	Benzodiazepines	Other
(DSLTMJNA)	*(DSLTALCO)*	*(DSLTCOCA)*	*(DSLTAMPH)*	*(DSLTOPIA)*	*(DSLTBENZ)*	*(DSLOTHR)*

Present for marijuana in the last 30 days?*(DSLTMJ30)* ☐ No ☐ Yes

A6 Have you had times when you would use (drug) so often that you used (drug) instead of working or spending time in hobbies with your family or friends? *Important social, occupational, or recreational activities given up or reduced because of substance abuse.*

Marijuana	Alcohol	Cocaine	Amphetamines	Opioids	Benzodiazepines	Other
(DSOFMJNA)	*(DSOFALCO)*	*(DSOFCOCA)*	*(DSOFAMPH)*	*(DSOFOPIA)*	*(DSOFBENZ)*	*(DSOFOTHR)*

Present for marijuana in the last 30 days?*(DSOFMJ30)* ☐ No ☐ Yes

A7 IF NOT ALREADY KNOWN, has (drug) caused psychological problems, like making you depressed? IF NOT ALREADY KNOWN, has (drug) ever caused physical problems or made a physical problem worse? IF YES TO EITHER OF THE ABOVE, did you keep on using (drug) anyway? *Continued substance use despite knowledge of having persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the use of the substance (e.g., continued drinking despite worsening ulcer).*

Marijuana	Alcohol	Cocaine	Amphetamines	Opioids	Benzodiazepines	Other
(DSPPMJNA)	*(DSPPALCH)*	*(DSPPCOCA)*	*(DSPPAMPH)*	*(DSPPOPIA)*	*(DSPPBENZ)*	*(DSPPOTHR)*

Present for marijuana in the last 30 days?*(DSPPMJ30)* ☐ No ☐ Yes

	Marijuana	Alcohol	Cocaine	Amphetamines	Opioids	Benzodiazepines	Other
Number of "Present" responses for each column. Dependence is indicated by a total of 3 or more.	*(DSDPRMJN)* *(x)*	*(DSDPRALC)* *(x)*	*(DSDPRCOC)* *(x)*	*(DSDPRAMP)* *(x)*	*(DSDPROPI)* *(x)*	*(DSDPRBNZ)* *(x)*	*(DSDPROTR)* *(x)*
How old were you the first time you experienced three or more of these symptoms?	*(DSDAGMAH)* *(xx)*	*(DSDAGALC)* *(xx)*	*(DSDAGCOC)* *(xx)*	*(DSDAGOTR)* *(xx)*	*(DSDAGOPI)* *(xx)*	*(DSDAGBNZ)* *(xx)*	*(DSDAGOTH)* *(xx)*

Number of "Present for marijuana in the last 30 days" responses. *(DSUSEMJT)* *(x)*

Substance ABUSE Criteria

Now I'd like to ask for a few more questions about your use of (drug)
A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by **one** (or more) of the following, occurring at any time within the same 12-month period.

B1 Have you often been intoxicated or high or very hungover with (drug) while you were doing something important like being at school or work, or taking care of children? IF NO: What about missing something important, like staying away from school or work or missing an appointment because you were intoxicated, high, or very hungover? IF YES AND UNKNOWN, how often? (Over what period of time?) *Recurrent substance use resulting in a failure to fulfill major role obligations at work, school, or home (e.g., repeated absences or poor work performance related to substance use; substance-related absences, suspensions, or expulsions from school, neglect of children or household).*

Marijuana	Alcohol	Cocaine	Amphetamines	Opioids	Benzodiazepines	Other
(DSHOMJNA)	*(DSHOALCO)*	*(DSHOCOCA)*	*(DSHOAMPH)*	*(DSHOOPIA)*	*(DSHOBENZ)*	*(DSHOOTHR)*

Present for marijuana in the last 30 days?*(DSHOMJ30)* ☐ No ☐ Yes

B2 Have you ever used (drug) in a situation in which it might have been dangerous to use (drug) at all? (Have you ever driven while you were really too high to drive?) IF YES AND UNKNOWN: How often? (Over what period of time?) *Recurrent substance use in situations in which it is physically hazardous (e.g., driving an automobile or operating a machine when impaired by substance use).*

Marijuana	Alcohol	Cocaine	Amphetamines	Opioids	Benzodiazepines	Other
(DSDNMJNA)	*(DSDNALCO)*	*(DSDNCOCA)*	*(DSDNAMPH)*	*(DSDNOPIA)*	*(DSDNBENZ)*	*(DSDNOTHR)*

Present for marijuana in the last 30 days?*(DSDNMJ30)* ☐ No ☐ Yes

B3 Has your use of (drug) ever gotten you into trouble with the law? IF YES AND UNKNOWN: How often? (Over what period of time?) *Recurrent substance-related legal problems (e.g., arrests for substance-related disorderly conduct).*

Marijuana	Alcohol	Cocaine	Amphetamines	Opioids	Benzodiazepines	Other
(DSTLMJNA)	*(DSTLALCO)*	*(DSTLCOCA)*	*(DSTLAMPH)*	*(DSTLOPIA)*	*(DSTLBENZ)*	*(DSTLOTHR)*

B4 Has your use of (drug) caused problems with other people, such as with family members, friends, or people at work? (Did you ever get into physical fights or bad arguments about your drug use?) IF YES: Did you keep on using (drug) anyway? (Over what period of time?) *Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance (e.g., arguments with spouse about consequences of intoxication, physical fights).*

Marijuana	Alcohol	Cocaine	Amphetamines	Opioids	Benzodiazepines	Other
(DSPBMJNA)	*(DSPBALCO)*	*(DSPBCOCA)*	*(DSPBAMPH)*	*(DSPBOPIA)*	*(DSPBBENZ)*	*(DSPBOTHR)*

Present for marijuana in the last 30 days?*(DSPBMJ30)* ☐ No ☐ Yes

	Marijuana	Alcohol	Cocaine	Amphetamines	Opioids	Benzodiazepines	Other
Number of "Present" responses for each column. Abuse is indicated by a total of 1 or more.	*(DSAPRMJN)* *(x)*	*(DSAPRALC)* *(x)*	*(DSAPRCOC)* *(x)*	*(DSAPROTS)* *(x)*	*(DSAPROPI)* *(x)*	*(DSAPRBNZ)* *(x)*	*(DSAPROTR)* *(x)*
How old were you the first time you experienced one or more of these symptoms?	*(DSAAGMAH)* *(xx)*	*(DSAAGALC)* *(xx)*	*(DSAAGCOC)* *(xx)*	*(DSAAGOTS)* *(xx)*	*(DSAAGOPI)* *(xx)*	*(DSAABENZ)* *(xx)*	*(DSAAGOTH)* *(xx)*

Additional DSM-V Criterion

C1 Have you experienced craving or a strong desire or urge to use (drug)?

Marijuana	Alcohol	Cocaine	Amphetamines	Opioids	Benzodiazepines	Other
(DSCRMJNA)	*(DSCRALCH)*	*(DSCRCOCA)*	*(DSCRAMPH)*	*(DSCROPIA)*	*(DSCRBENZ)*	*(DSCROTHR)*

Present for marijuana in the last 30 days?*(DSCRMJ30)* ☐ No ☐ Yes

NIDA Clinical Trials Network

0053A (ENR)

Web Version: 1.0; 2.00; 11-24-14

Date informed consent signed:*(S2CNSTDT)* *(mm/dd/yyyy)*

Pre-screening ID:*(S2SCRNID)* *(xxxx)*

Comments:*(S2COMM)*

NIDA Clinical Trials Network

Fagerstrom Test for Nicotine Dependence (FND)

Web Version: 1.0; 1.01; 10-21-13

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment:*(FNDASMDT)* _____ *(mm/dd/yyyy)*

Do you currently smoke cigarettes?*(FNSMOKE)* ☐ No ☐ Yes

If "Yes", read each question below. For each question enter the answer choice which best describes your responses.

1. How soon after you wake up do you smoke your first cigarette?*(FNFIRST)* _____

2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in cinema, etc.)?*(FNFORBDN)* ☐ No ☐ Yes

3. Which cigarette would you hate most to give up?*(FNGIVEUP)* ☐ The first one in the morning ☐ All others

4. How many cigarettes/day do you smoke?*(FNNODAY)* _____

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?*(FNFREQ)* ☐ No ☐ Yes

6. Do you smoke if you are so ill that you are in bed most of the day?*(FNSICK)* ☐ No ☐ Yes

Heatherton TF; Kozlowski LT; Frecker RC; The Fagerström Test for Nicotine Dependence: a revision of the Fagerström Tolerance Questionnaire. *Br J Addict* (1991), 86, 119-1127.

NIDA Clinical Trials Network

Hospital Anxiety and Depression Scale (HAD)

Web Version: 1.0; 2.00; 09-10-15

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment:*(HADASMDT)* *(mm/dd/yyyy)*

*This questionnaire will help your physician to know how you are feeling. Read every sentence. Pick an answer that best describes how you have been feeling during the **LAST WEEK**. You do not have to think too much to answer. In this questionnaire, spontaneous answers are more important.*

1. I feel tense or wound up:*(HATENSE)*
2. I still enjoy the things I used to enjoy:*(HAENJOY)*
3. I get a sort of frightened feeling as if something awful is about to happen: *(HAAWFUL)*
4. I can laugh and see the funny side of things:*(HALAUGH)*
5. Worrying thoughts go through my mind:*(HAWORRY)*
6. I feel cheerful:*(HACHERFL)*
7. I can sit at ease and feel relaxed:*(HARELXD)*
8. I feel as if I am slowed down:*(HASLOWDN)*
9. I get a sort of frightened feeling like "butterflies" in the stomach:*(HABTRFLY)*

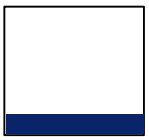
10. I have lost interest in my appearance: *(HALOOKS)*

11. I feel restless, as if I have to be on the move: *(HARSTLS)*

12. I look forward with enjoyment to things: *(HAFORWRD)*

13. I get sudden feelings of panic: *(HAPANIC)*

14. I can enjoy a good book or radio or TV program: *(HALIKETV)*



NIDA Clinical Trials Network

Self-Report of HIV Testing (HIV)

Web Version: 1.0; 1.03; 04-15-14

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment:*(HIVASMDT)* _____ *(mm/dd/yyyy)*

An HIV test checks whether someone has the virus that causes AIDS.

1. Have you ever been tested for HIV?*(HIHIVTST)*

2. When did you have your most recent HIV test?*(HITESTMO)* _____ *(xx)* month *(HITESTYR)*/ _____ *(xxxx)* year

3. What was the result of your most recent HIV test?*(HIRESULT)*

4. Which of these best describes the <u>most important reason</u> you have not been tested for HIV in the past 12 months?*(HINORESN)*

Additional Selection Options for HIV

What was the result of your most recent HIV test?
97-Don't know

NIDA Clinical Trials Network

Marijuana Craving Questionnaire (MCQ)

Web Version: 1.0; 1.01; 03-20-14

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment:*(MCQASMDT)* _____ *(mm/dd/yyyy)*

Indicate how strongly you agree or disagree with each of the following statements by checking one of the spaces between STRONGLY DISAGREE and STRONGLY AGREE. The closer you place your check mark to one end or the other indicates the strength of your agreement or disagreement. If you don't agree or disagree with a statement, place your check mark in the middle space. Please complete every item. We are interested in how you are thinking or feeling right now as you are filling out the questionnaire.

		Strongly Disagree						Strongly Agree
1. Smoking marijuana would be pleasant right now.	*(MCPLEAS)*	☐	☐	☐	☐	☐	☐	☐
2. I could not easily limit how much marijuana I smoked right now.	*(MCLIMIT)*	☐	☐	☐	☐	☐	☐	☐
3. Right now, I am making plans to use marijuana.	*(MCPLANS)*	☐	☐	☐	☐	☐	☐	☐
4. I would feel more in control of things right now if I could smoke marijuana.	*(MCCONTRL)*	☐	☐	☐	☐	☐	☐	☐
5. Smoking marijuana would help me sleep better at night.	*(MCSLEEP)*	☐	☐	☐	☐	☐	☐	☐
6. If I smoked marijuana right now, I would feel less tense.	*(MCTENSE)*	☐	☐	☐	☐	☐	☐	☐
7. I would not be able to control how much marijuana I smoked if I had some here.	*(MCNOCTRL)*	☐	☐	☐	☐	☐	☐	☐
8. It would be great to smoke marijuana right now.	*(MCGREAT)*	☐	☐	☐	☐	☐	☐	☐
9. I would feel less anxious if I smoked marijuana right now.	*(MCANXOUS)*	☐	☐	☐	☐	☐	☐	☐
10. I need to smoke marijuana now.	*(MCNEED)*	☐	☐	☐	☐	☐	☐	☐
11. If I were smoking marijuana right now, I would feel less nervous.	*(MCNERVUS)*	☐	☐	☐	☐	☐	☐	☐
12. Smoking marijuana would make me content.	*(MCCONTNT)*	☐	☐	☐	☐	☐	☐	☐

NIDA Clinical Trials Network

Medical and Psychiatric History (MHX)

Web Version: 1.0; 4.02; 08-05-15

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment:*(MHXASMDT)* _____ *(mm/dd/yyyy)*

Medical History

Condition	History of the Condition:	If "Yes", specify:	Condition Present Currently:
1. Eye disorders:	*(MHEYEH)* ☐ No ☐ Yes	*(MHEYESP)*	*(MHEYEC)* ☐ No ☐ Yes
2. Ear disorders:	*(MHEARH)* ☐ No ☐ Yes	*(MHEARSP)*	*(MHEARC)* ☐ No ☐ Yes
3. Respiratory and throat disorders:	*(MHRESPH)* ☐ No ☐ Yes	*(MHRESPSP)*	*(MHRESPC)* ☐ No ☐ Yes
4. Cardiovascular disorders:	*(MHCARDH)* ☐ No ☐ Yes	*(MHCARDSP)*	*(MHCARDC)* ☐ No ☐ Yes
5. Liver and gallbladder disorders:	*(MHLIVRH)* ☐ No ☐ Yes	*(MHLIVRSP)*	*(MHLIVRC)* ☐ No ☐ Yes
6. Other gastrointestinal disorders:	*(MHGIH)* ☐ No ☐ Yes	*(MHGISP)*	*(MHGIC)* ☐ No ☐ Yes
7. Skin disorders:	*(MHSKINH)* ☐ No ☐ Yes	*(MHSKINSP)*	*(MHSKINC)* ☐ No ☐ Yes
8. Musculoskeletal disorders:	*(MHMUSCH)* ☐ No ☐ Yes	*(MHMUSCSP)*	*(MHMUSCC)* ☐ No ☐ Yes
9. Metabolic disorders:	*(MHMETAH)* ☐ No ☐ Yes	*(MHMETASP)*	*(MHMETAC)* ☐ No ☐ Yes
10. Endocrine disorders:	*(MHENDOH)* ☐ No ☐ Yes	*(MHENDOSP)*	*(MHENDOC)* ☐ No ☐ Yes
11. Renal and urinary tract disorders:	*(MHRENLH)* ☐ No ☐ Yes	*(MHRENLSP)*	*(MHRENLC)* ☐ No ☐ Yes
12. Reproductive system and breast disorders:	*(MHREPOH)* ☐ No ☐ Yes	*(MHREPOSP)*	*(MHREPOC)* ☐ No ☐ Yes
13. Epilepsy or seizure disorder:	*(MHELPYH)* ☐ No ☐ Yes	*(MHELPYSP)*	*(MHELPYC)* ☐ No ☐ Yes

14. Clinically significant neurological damage:	*(MHNEURH)* ☐ No ☐ Yes	*(MHNEURSP)*	*(MHNEURC)* ☐ No ☐ Yes
15. Other nervous system disorders:	*(MHNERVH)* ☐ No ☐ Yes	*(MHNERVSP)*	*(MHNERVC)* ☐ No ☐ Yes

Psychiatric History

Condition	History of the Condition:	If "Yes", specify:	Condition Present Currently:
16. Homicidal ideation:	*(MHHIDH)* ☐ No ☐ Yes	*(MHHIDSP)*	*(MHHIDC)* ☐ No ☐ Yes
17. Homicidal behavior:	*(MHHBEHH)* ☐ No ☐ Yes	*(MHHBEHSP)*	*(MHHBEHC)* ☐ No ☐ Yes

Other Conditions not Listed Above	Specific Details:	Condition Present Currently:
18. *(MHOTHR1)*	*(MHOTHR1S)*	*(MHOTHR1C)* ☐ No ☐ Yes
19. *(MHOTHR2)*	*(MHOTHR2S)*	*(MHOTHR2C)* ☐ No ☐ Yes
20. *(MHOTHR3)*	*(MHOTHR3S)*	*(MHOTHR3C)* ☐ No ☐ Yes

21. Does the participant have a history of surgical and/or medical procedures?*(MHSURGRY)* ☐ No ☐ Yes

If the participant has had major surgery, provide most important/significant surgical event data below, including date of surgery.
If the participant remembers only the year, then record "06" for the month and "15" for the day. If the participant remembers only the month and year, then record "15" for the day.

Type of Surgery and/or Medical Procedure	Surgery/Procedure Date: *(mm/dd/yyyy)*
22.*(MHSRG1)*	*(MHSRG1DT)*
23.*(MHSRG2)*	*(MHSRG2DT)*
24.*(MHSRG3)*	*(MHSRG3DT)*
25.*(MHSRG4)*	*(MHSRG4DT)*
26.*(MHSRG5)*	*(MHSRG5DT)*

Chronic Pain History

27. Does the participant have chronic pain that is pain lasting longer than 6 months?*(MHPAIN6M)* ☐ No ☐ Yes
28. On an average day with chronic pain, how would the participant describe their pain with 0 (zero) being no pain and 10 being the worst pain imaginable?*(MHAVPAIN)* *(xx)*
29. How long has the participant had chronic pain?*(MHTMPAIN)*

Medical History - Specific Study Eligibility Criteria

30. Does the participant have an allergy or intolerance to NAC?*(MHDRGALG)* ☐ No ☐ Yes
31. Does the participant have a recent history of asthma (within the last 3 years)?*(MHMEDCON)* ☐ No ☐ Yes
32. Does the participant have a history of seizure disorder, bipolar disorder, schizophrenia, or other significant or unstable medical or psychiatric illness that may place the participant at increased risk in the judgment of the medical clinician?*(MHMEDCO2)* ☐ No ☐ Yes
33. Does the participant show signs of significant risk of homicide or suicide?*(MHSUICDE)* ☐ No ☐ Yes

Comments:*(MHXCOMM)*

NIDA Clinical Trials Network

MINI (MIN)

Web Version: 1.0; 2.00; 01-09-14

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment:*(MINASMDT)* _____ *(mm/dd/yyyy)*

	MODULES	TIME FRAME	MEETS CRITERIA
A	MAJOR DEPRESSIVE EPISODE	Current (2 weeks)	*(MIMDPCUR)* ☐ No ☐ Yes ☐ Not explored/module not completed
		Past	*(MIMDPPST)* ☐ No ☐ Yes ☐ Not explored/module not completed
		Recurrent	*(MIMDPREC)* ☐ No ☐ Yes ☐ Not explored/module not completed
	MAJOR DEPRESSIVE DISORDER	Current (2 weeks)	*(MIMDDCUR)* ☐ No ☐ Yes ☐ Not explored/module not completed
		Past	*(MIMDDPST)* ☐ No ☐ Yes ☐ Not explored/module not completed
		Recurrent	*(MIMDDREC)* ☐ No ☐ Yes ☐ Not explored/module not completed
C	MANIC EPISODE	Current	*(MIMANICC)* ☐ No ☐ Yes ☐ Not explored/module not completed
		Past	*(MIMANICP)* ☐ No ☐ Yes ☐ Not explored/module not completed
	HYPOMANIC EPISODE	Current	*(MIHYPOMC)* ☐ No ☐ Yes ☐ Not explored/module not completed
		Past	*(MIHYPOMP)* ☐ No ☐ Yes ☐ Not explored/module not completed
	BIPOLAR I DISORDER	Current	*(MIBD1CUR)* ☐ No ☐ Yes ☐ Not explored/module not completed
		Past	*(MIBD1PST)* ☐ No ☐ Yes ☐ Not explored/module not completed
	BIPOLAR II DISORDER	Current	*(MIBD2CUR)* ☐ No ☐ Yes ☐ Not explored/module not completed
		Past	*(MIBD2PST)* ☐ No ☐ Yes ☐ Not explored/module not completed
	BIPOLAR DISORDER NOS	Current	*(MIBDOCUR)* ☐ No ☐ Yes ☐ Not explored/module not completed
		Past	*(MIBDOPST)* ☐ No ☐ Yes ☐ Not explored/module not completed
D	PANIC DISORDER	Current (Past Month)	*(MIPANICC)* ☐ No ☐ Yes ☐ Not explored/module not completed
		Lifetime	*(MIPANICL)* ☐ No ☐ Yes ☐ Not explored/module not completed
E	AGORAPHOBIA	Current	*(MIAGORAP)* ☐ No ☐ Yes ☐ Not explored/module not completed
F	SOCIAL PHOBIA (Social Anxiety Disorder)	Current (Past Month)	*(MISOCPHC)* ☐ No ☐ Yes ☐ Not explored/module not completed
		Generalized	*(MISOCPHG)* ☐ No ☐ Yes ☐ Not explored/module not completed
		Non-generalized	*(MISOCPHN)* ☐ No ☐ Yes ☐ Not explored/module not completed
G	OBSESSIVE-COMPULSIVE DISORDER	Current (Past Month)	*(MIOCD)* ☐ No ☐ Yes ☐ Not explored/module not completed
H	POSTTRAUMATIC STRESS DISORDER	Current (Past Month)	*(MIPTSD)* ☐ No ☐ Yes ☐ Not explored/module not completed
K	PSYCHOTIC DISORDERS	Lifetime	*(MIPSYCLT)* ☐ No ☐ Yes ☐ Not explored/module not completed
		Current	*(MIPSYCCR)* ☐ No ☐ Yes ☐ Not explored/module not completed
	MOOD DISORDER WITH PSYCHOTIC FEATURES	Lifetime	*(MIMODDSL)* ☐ No ☐ Yes ☐ Not explored/module not completed

		Current	*(MIMODDSC)* ☐ No ☐ Yes ☐ Not explored/module not completed
L	ANOREXIA NERVOSA	Current (Past 3 Months)	*(MIANOREX)* ☐ No ☐ Yes ☐ Not explored/module not completed
M	BULIMIA NERVOSA	Current (Past 3 Months)	*(MIBULIMI)* ☐ No ☐ Yes ☐ Not explored/module not completed
	ANOREXIA NERVOSA, BINGE EATING/PURGING TYPE	Current	*(MIANXBEP)* ☐ No ☐ Yes ☐ Not explored/module not completed
N	GENERALIZED ANXIETY DISORDER	Current (Past 6 Months)	*(MIANXIET)* ☐ No ☐ Yes ☐ Not explored/module not completed
P	ANTISOCIAL PERSONALITY DISORDER	Lifetime	*(MISOCIAL)* ☐ No ☐ Yes ☐ Not explored/module not completed
Q	ATTENTION DEFICIT/HYPERACTIVITY DISORDER	Combined	*(MIADHDC)* ☐ No ☐ Yes ☐ Not explored/module not completed
		Inattentive	*(MIADHDI)* ☐ No ☐ Yes ☐ Not explored/module not completed
		Hyperactive/Impulsive	*(MIADHDHY)* ☐ No ☐ Yes ☐ Not explored/module not completed

Comments:*(MINCOMM)*

NIDA Clinical Trials Network

Marijuana Problem Scale (MPS)

Web Version: 1.0; 1.01; 03-21-14

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment:*(MPSASMDT)* _____ *(mm/dd/yyyy)*

*Following are different types of problems you may have experienced as a result of smoking marijuana. Please select the box that indicates whether this has been a problem for you in the **past 30 days**.*

Has marijuana caused you...

		No Problem	Minor Problem	Serious Problem
1.	Problems between you and your partner:	*(MPPARTNR)* ☐	☐	☐
2.	Problems in your family:	*(MPFAMILY)* ☐	☐	☐
3.	To neglect your family:	*(MPNEGLCT)* ☐	☐	☐
4.	Problems between you and your friends:	*(MPFRIEND)* ☐	☐	☐
5.	To miss days at work or miss classes:	*(MPMISSWK)* ☐	☐	☐
6.	To lose a job:	*(MPJOB)* ☐	☐	☐
7.	To have lower productivity:	*(MPPROD)* ☐	☐	☐
8.	Medical problems:	*(MPMED)* ☐	☐	☐
9.	Withdrawal symptoms:	*(MPWITH)* ☐	☐	☐
10.	Blackouts or flashbacks:	*(MPBLACK)* ☐	☐	☐
11.	Memory loss:	*(MPMEMORY)* ☐	☐	☐
12.	Difficulty sleeping:	*(MPSLEEP)* ☐	☐	☐
13.	Financial difficulties:	*(MPMONEY)* ☐	☐	☐
14.	Legal problems:	*(MPLEGAL)* ☐	☐	☐
15.	To have lower energy level:	*(MPENERGY)* ☐	☐	☐
16.	To feel bad about your use:	*(MPBADUSE)* ☐	☐	☐
17.	Lowered self-esteem:	*(MPESTEEM)* ☐	☐	☐
18.	To procrastinate:	*(MPPROCR)* ☐	☐	☐
19.	To lack self-confidence:	*(MPCONFID)* ☐	☐	☐

NIDA Clinical Trials Network

Obsessive Compulsive Drug Use - Marijuana (OCM)

Web Version: 1.0; 1.01; 03-24-14

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment: *(OCMASMDT)* *(mm/dd/yyyy)*

The questions below ask you about your marijuana use and your attempts to control your use. For each question, indicate the statement that best applies to you.

1. How much of your time when you are not using is occupied by ideas, thoughts, impulses, or images related to the use of marijuana? *(OCTKTIME)*

2. How frequently do these thoughts related to marijuana occur? *(OCTKFREQ)*

3. How much do these thoughts related to marijuana interfere with your social or work functioning? *(OCTKSOCL)*

4. How much distress or disturbances do these ideas, thoughts, impulses, or images related to marijuana cause you when you are not taking marijuana? *(OCDISTRS)*

5. How much of an effort do you make to resist these thoughts related to marijuana or try to disregard or turn your attention away from these thoughts? *(Rate your efforts to resist these thoughts, not your success in controlling them)(OCRESIST)*

6. How successful are you in stopping or diverting these thoughts related to marijuana? *(OCDIVERT)*

7. If you do not use, how often do you feel the urge or drive to use marijuana? *(OCURGEOF)*

8. If you do not use, how much time of the day do you feel the urge or drive to use marijuana? *(OCURGETM)*

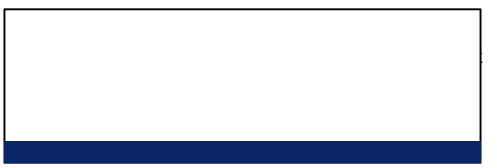
9. How much does the urge to use marijuana interfere with your social life or your occupational activities? *(OCURGESC)*

10. If you were prevented from using marijuana when you desired to use it, how anxious or upset would you become? *(OCUPSET)*

11. How much of an effort do you make to resist the use of marijuana? *(OCEFFORT)*

12. How strong was the drive to use marijuana in the past week? *(OCSTRONG)*

13. How much control do you have over your marijuana use? *(OCCONTRL)*



NIDA Clinical Trials Network

Pregnancy and Birth Control Assessment (PBC)

Web Version: 1.0; 3.02; 12-09-14

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Complete this form only for females.

Date of assessment:*(PBCASMDT)* _____ *(mm/dd/yyyy)*

1. Is the participant breastfeeding?*(PBBSTFED)* ☐ No ☐ Yes
2. Does the participant agree to use an acceptable method of birth control? *(PBUSEBC)* ☐ No ☐ Yes

   If "Yes", select all that apply:

   a. Oral contraceptives:*(PBORALCN)* ☐ No ☐ Yes
   b. Contraceptive patch:*(PBPATCH)* ☐ No ☐ Yes
   c. Barrier (diaphragm or condom):*(PBBARRIR)* ☐ No ☐ Yes
   d. Levonorgestrel implant:*(PBLEVIMP)* ☐ No ☐ Yes
   e. Medroxyprogesterone acetate injection:*(PBMEDINJ)* ☐ No ☐ Yes
   f. Complete abstinence from sexual intercourse:*(PBABSTIN)* ☐ No ☐ Yes
   g. Hormonal vaginal contraceptive ring:*(PBRING)* ☐ No ☐ Yes
   h. Surgical sterilization:*(PBSURGSZ)* ☐ No ☐ Yes
   i. Other:*(PBBCOTH)* ☐ No ☐ Yes

      If "Other", specify:*(PBBCOSP)* _____

3. Was a pregnancy test performed?*(PBPRGTST)* ☐ No ☐ Yes

   a. Date of pregnancy test:*(PBPTSTDT)* _____ *(mm/dd/yyyy)*
   b. Result of pregnancy test:*(PBRESULT)* ☐ Negative ☐ Positive

Comments:*(PBCCOMM)*

NIDA Clinical Trials Network

Prior and Concomitant Medications (PCM)

Web Version: 1.0; 1.00; 10-04-13

Medication name *(PCMEDNME)*:
Medication start date *(PCSTRTDT)*:

1. Indication for use: *(PCINDICT)*

If "Other," specify: *(PCINDOTH)*

2. Was this medication used to treat an adverse event? *(PCMEDAE)* ☐ No ☐ Yes

3. Is medication ongoing? *(PCONGOIN)* ☐ No ☐ Yes ☐ Yes (continuing at protocol completion or study termination)

If "No", specify date medication was discontinued or changed: *(PCTERMDT)* *(mm/dd/yyyy)*

Comments: *(PCMCOMM)*

Additional Selection Options for PCM

Indication for use:
05A---Diabetes
06A---Vitamins
07A---Mineral
99B-BLOOD AND BLOOD FORMING ORGANS
01B---Aspirin/coumadin/heparin
02B---Antianemic
03B---Blood products/IV fluids
99C-CARDIOVASCULAR SYSTEM
01C---Antihypertensives
02C---Diuretics
03C---Beta blocking
04C---Calcium Channel
05C---Lipid modifying agents
01D-ALL SKIN CREAMS
01G-CONTRACEPTIVES/ED/SEX HORMONES
01H-STEROIDS/THYROID HORMONES
01J-ANTIBACTERIAL/ANTIVIRAL/ANTIFUNGAL/TB/VACCINES
99M-MUSCULOSKELETAL SYSTEM
01M---Antiinflammatory and antirheumatic
02M---Muscle relaxants
03M---Antigout
99N-NERVOUS SYSTEM
01N---Analgesics including antipyretics
02N---Antiepileptics
03N---Anxiety/Depression/Sleep
99R-RESPIRATORY SYSTEM
01R---Nasal
02R---Throat
03R---Obstructive airway
04R---Cough and cold
05R---Antihistamines
01S-EYE AND EAR DROPS
Z01-VARIOUS
01V---Allergens
02V---All other therapeutic products
03V---Diagnostic agents
04V---General nutrients
05V---All other non-therapeutic products
06V---Contrast media
07V---Diagnostic radiopharmaceuticals
08V---Therapeutic radiopharmaceuticals
99-OTHER

NIDA Clinical Trials Network

Protocol Deviation Review (PDR)

Web Version: 1.0; 2.00; 03-24-14

Date of deviation *(PDDATE)*:
Protocol deviation number *(PDSEQNUM)*:

Completed by Protocol Specialist:

1. What section of the protocol does this deviation refer to?*(PDSECTN)*

2. Does the report of this deviation require site staff retraining?*(PDTRAIN)* ☐ No ☐ Yes
   If "Yes", specify plan for retraining:*(PDPLATRA)*

3. Deviation was discussed with Lead Investigative Team on:*(PDDISCDT)* *(mm/dd/yyyy)*

4. Deviation is categorized as:*(PDCATGRY)* ☐ Major ☐ Minor

5. Deviation assessment by Protocol Specialist complete:*(PDPSCMP)* ☐ No ☐ Yes
   Protocol Specialist reviewer:*(PDPSRVID)* (initials)

Completed by Protocol Monitor:

6. Corrective action for this deviation was completed and documented on-site as described:*(PDACTDOC)* ☐ No ☐ Yes
   If "No", specify reason:*(PDSITESP)*

7. Deviation was reported to the IRB as required:*(PDIRBRPT)* ☐ No ☐ Yes

If "No", specify reason: *(PDIRBSP)*

8. Preventive action plan related to this event was completed and documented on-site as described: *(PDPREVNT)*
   ☐ No ☐ Yes
9. Review by Protocol Monitor is complete: *(PDPMCMP)*
   ☐ No ☐ Yes

   Protocol Monitor reviewer: *(PDPMRVID)* (initials)

Comments: *(PVCOMM)*

Additional Selection Options for PDR

Protocol deviation number *(PDSEQNUM)* (key field):
01-1st Protocol Deviation of the day
02-2nd Protocol Deviation of the day
03-3rd Protocol Deviation of the day
04-4th Protocol Deviation of the day
05-5th Protocol Deviation of the day
06-6th Protocol Deviation of the day
07-7th Protocol Deviation of the day
08-8th Protocol Deviation of the day
09-9th Protocol Deviation of the day
10-10th Protocol Deviation of the day

NIDA Clinical Trials Network

Protocol Deviation (PDV)

Web Version: 1.0; 1.00; 03-21-14

Date of deviation *(PDDATE)*:
Protocol deviation number *(PDSEQNUM)*:

1. Date deviation identified:*(PDVDATE)* *(mm/dd/yyyy)*

2. Deviation type:*(PDTYPE)*

If "Other", specify:*(PDTYPSP)*

3. Brief description of what occurred:*(PDDESCPT)*

4. Brief description of the actual or expected corrective action for this event:*(PDACTION)*

5. Brief description of the plan to prevent recurrence:*(PDPREVRE)*

6. Is this deviation reportable to your IRB?*(PDIRBREP)* ☐ No ☐ Yes

If "Yes", will the IRB be notified at the time of continuing review?*(PDIRBCON)* ☐ No ☐ Yes

If "Yes", date of planned submission:*(PDIRBPDT)* *(mm/dd/yyyy)*

If "No", date of actual submission:*(PDIRBADT)* *(mm/dd/yyyy)*

Comments:*(PDVCOMM)*

Additional Selection Options for PDV

Protocol deviation number *(PDSEQNUM)* (key field):
01-1st Protocol Deviation of the day
02-2nd Protocol Deviation of the day
03-3rd Protocol Deviation of the day
04-4th Protocol Deviation of the day
05-5th Protocol Deviation of the day
06-6th Protocol Deviation of the day
07-7th Protocol Deviation of the day
08-8th Protocol Deviation of the day
09-9th Protocol Deviation of the day
10-10th Protocol Deviation of the day

Deviation type:
01E--- Informed consent process not properly conducted and/or documented
01Z--- Other (specify)
Z02-INCLUSION/EXCLUSION CRITERIA
02A--- Ineligible participant randomized/inclusion/exclusion criteria not met
02Z--- Other (specify)
Z04-LABORATORY ASSESSMENTS
04A--- Biologic specimen not collected/processed as per protocol
04Z--- Other (specify)
Z05-STUDY PROCEDURES/ASSESSMENTS
05A--- Protocol required visit/assessment not scheduled or conducted
05B--- Study assessments not completed/followed as per protocol
05C--- Inappropriate unblinding
05Z--- Other (specify)
Z06-ADVERSE EVENT
06A--- AE not reported
06B--- SAE not reported
06C--- AE/SAE reported out of protocol specified reporting timeframe
06D--- AE/SAE not elicited, observed and/or documented as per protocol
06E--- Safety assessment (e.g. labs, ECG, clinical referral to care) not conducted per protocol
06Z--- Other (specify)
Z07-RANDOMIZATION PROCEDURES
07A--- Stratification error
07Z--- Other (specify)
Z08-STUDY MEDICATION MANAGEMENT
08A--- Medication dispensed to ineligible participant
08B--- Medication dispensed to incorrect participant
08C--- Medication dosing errors (protocol specified dose not dispensed)
08D--- Participant use of protocol prohibited medication
08Z--- Other (specify)
Z09-STUDY BEHAVIORAL INTERVENTION
09A--- Study behavioral intervention was not provided/performed as per protocol
09Z--- Other (specify)
Z99-OTHER SIGNIFICANT DEVIATIONS
99A--- Destruction of study materials without prior authorization from sponsor
99B--- Breach of Confidentiality
99Z--- Other (specify)

NIDA Clinical Trials Network

Physical Examination (PEX)

Web Version: 1.0; 2.00; 11-19-13

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment:*(PEXASMDT)* *(mm/dd/yyyy)*

Comments

General appearance: *(PEGENAPP)*

(PEGASP)

Skin, hair, and nails: *(PESKHRNA)*

(PESHNSP)

Head and neck:

(PEHDNK)

(PEHDNKSP)

Ears, eyes, nose, and throat:

(PEENT)

(PEENTSP)

Cardiovascular:

(PECARD)

(PECARDSP)

Respiratory:

(PERESP)

(PERESPSP)

Gastrointestinal:

(PEGAST)

(PEGASTSP)

Extremities:

(PEEXTR)

(PEEXTRSP)

Lymph nodes:

(PELYMP)

(PELYMPSP)

Musculoskeletal:

(PEMUSC)

(PEMUSCSP)

Neurological: *(PENEUR)*

(PENEURSP)

Other (specify in comments): *(PEOTHER)*

(PEOTHESP)

Comments:*(PEXCOMM)*

NIDA Clinical Trials Network

Pittsburgh Sleep Quality Index (PSQ)

Web Version: 1.0; 1.02; 03-17-15

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment:*(PSQASMDT)* _____ *(mm/dd/yyyy)*

Instructions: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, what time (in 24-hour format) have you usually gone to bed at night?*(PSBEDHR)* _____ *(hh:mm)*
2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?*(PSBEDMIN)* _____ *(xxx)* minutes
3. During the past month, what time (in 24-hour format) have you usually gotten up in the morning?*(PSAWAKE)* _____ *(hh:mm)*
4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.)*(PSHRSSLP)* _____ *(xx.xx)* hours

For each of the remaining questions, check the one best response. Please answer all questions.

5. During the past month, how often have you had trouble sleeping because you...

	Not During the Past Month	Less Than Once a Week	Once or Twice a Week	Three or More Times a Week
a. Cannot get to sleep within 30 minutes:	*(PSNOSLP)* ☐	☐	☐	☐
b. Wake up in the middle of the night or early morning:	*(PSWAKEUP)* ☐	☐	☐	☐
c. Have to get up to use the bathroom:	*(PSBATHRM)* ☐	☐	☐	☐
d. Cannot breathe comfortably:	*(PSBREATH)* ☐	☐	☐	☐
e. Cough or snore loudly:	*(PSSNORE)* ☐	☐	☐	☐
f. Feel too cold:	*(PSCOLD)* ☐	☐	☐	☐
g. Feel too hot:	*(PSHOT)* ☐	☐	☐	☐
h. Had bad dreams:	*(PSDREAMS)* ☐	☐	☐	☐
i. Have pain:	*(PSPAIN)* ☐	☐	☐	☐

j. Are there other reasons why during the past month you have had trouble sleeping?*(PSSLPOTR)* ☐ No ☐ Yes

i. If "Yes", specify:*(PSSLPSP)*

ii. How often during the past month have you had trouble sleeping because of this? *(PSOTRFRQ)* ☐ ☐ ☐ ☐

6. During the past month, how would you rate your sleep quality overall?*(PSSLPQLT)*

7. During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?*(PSSLPMED)*

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity? *(PSALERT)*

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?*(PSENTHUS)*

NIDA Clinical Trials Network

Pre-Screen Summary (PSS)

Web Version: 1.0; 1.00; 12-09-13

Pre-Screen ID *(PRESCNID)*:

Date of data entry:*(PSSASMDT)* *(mm/dd/yyyy)*

1. Referral Source:*(PSREFSOU)*

If "Other", specify:*(PSRSOTSP)*

2. Was the participant eligible from Pre-Screen? *(PSELIGPS)* ☐ No ☐ Yes

If "No", reason not eligible:*(PSNOELIG)*

If "Other", specify:*(PSOTELIG)*

3. If eligible, was the participant scheduled for a screening visit?*(PSPTSCHE)* ☐ No ☐ Yes

If "No", reason not scheduled:*(PSNOSCHE)*

If "Other", specify:*(PSNSCHSP)*

Comments:*(PSSCOMM)*

Additional Selection Options for PSS

Referral Source:
6-TV ad
7-Social media
8-Craigslist
9-Clinical referral
10-ClinicalTrials.gov
99-Other

If "No", reason not eligible:
6-Unwilling to stop taking NAC or supplement containing NAC during study participation
7-Allergy or intolerance to NAC
8-Currently taking carbamazepine or nitroglycerin
9-Use of synthetic cannabinoids (such as K2/Spice) in the last 30 days
10-Current substance dependence, other than cannabis or nicotine
11-Maintenance treatment with buprenorphine or methadone
12-Recent history of asthma (within 3 years)
13-Unstable medical or psychiatric illness (i.e., seizure disorder, bipolar disorder, schizophrenia)
99-Other

NIDA Clinical Trials Network

Quality of Life - PhenX (QLP)

Web Version: 1.0; 1.02; 01-03-14

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment:*(QLPASMDT)* _____ *(mm/dd/yyyy)*

1. Would you say that in general your health is:*(QLHEALTH)*

2. Now thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good?*(QLHLTNGD)* _____ *(xx)* Number of days

3. Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?*(QLMTLNG)* _____ *(xx)* Number of days

4. During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation?*(QLACT)* _____ *(xx)* Number of days

NIDA Clinical Trials Network

TLFB Assessment Period (TAP)

Web Version: 1.0; 3.02; 07-11-14

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment:*(TAPASMDT)* _____ *(mm/dd/yyyy)*

1. Assessment period:*(TATFSTDT)*
   From: _____ *(mm/dd/yyyy)*
   (TATFENDT)
   To: _____ *(mm/dd/yyyy)*

2. Have any illicit substances, alcohol, or cigarettes been taken during this assessment period?*(TASUBALC)*
   ☐ No ☐ Yes

Comments:*(TAPCOMM)*

NIDA Clinical Trials Network

Timeline Followback (T53)

Web Version: 1.0; 2.00; 07-24-14

TFB week start date *(TFWKSTDT)*:

Day	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Date	*(TLDATE1)*	*(TLDATE2)*	*(TLDATE3)*	*(TLDATE4)*	*(TLDATE5)*	*(TLDATE6)*	*(TLDATE7)*
1. Have any illicit substances, alcohol, or cigarettes been used on this day?	*(TLSUBAL1)* ☐ No ☐ Yes	*(TLSUBAL2)* ☐ No ☐ Yes	*(TLSUBAL3)* ☐ No ☐ Yes	*(TLSUBAL4)* ☐ No ☐ Yes	*(TLSUBAL5)* ☐ No ☐ Yes	*(TLSUBAL6)* ☐ No ☐ Yes	*(TLSUBAL7)* ☐ No ☐ Yes
2. Number of cigarettes *(xx)*:	*(TLNMCIG1)*	*(TLNMCIG2)*	*(TLNMCIG3)*	*(TLNMCIG4)*	*(TLNMCIG5)*	*(TLNMCIG6)*	*(TLNMCIG7)*
3. Alcohol number of standard drinks *(xx)*:	*(TLALCHL1)*	*(TLALCHL2)*	*(TLALCHL3)*	*(TLALCHL4)*	*(TLALCHL5)*	*(TLALCHL6)*	*(TLALCHL7)*
4. Cannabinoids/Marijuana method A:	*(TLTHCR11)*	*(TLTHCR12)*	*(TLTHCR13)*	*(TLTHCR14)*	*(TLTHCR15)*	*(TLTHCR16)*	*(TLTHCR17)*
Quantity *(xx.x)*:	*(TLTHCN11)*	*(TLTHCN12)*	*(TLTHCN13)*	*(TLTHCN14)*	*(TLTHCN15)*	*(TLTHCN16)*	*(TLTHCN17)*
5. Cannabinoids/Marijuana method B:	*(TLTHCR21)*	*(TLTHCR22)*	*(TLTHCR23)*	*(TLTHCR24)*	*(TLTHCR25)*	*(TLTHCR26)*	*(TLTHCR27)*
Quantity *(xx.x)*:	*(TLTHCN21)*	*(TLTHCN22)*	*(TLTHCN23)*	*(TLTHCN24)*	*(TLTHCN25)*	*(TLTHCN26)*	*(TLTHCN27)*
6. Cannabinoids/Marijuana method C:	*(TLTHCR31)*	*(TLTHCR32)*	*(TLTHCR33)*	*(TLTHCR34)*	*(TLTHCR35)*	*(TLTHCR36)*	*(TLTHCR37)*
Quantity *(xx.x)*:	*(TLTHCN31)*	*(TLTHCN32)*	*(TLTHCN33)*	*(TLTHCN34)*	*(TLTHCN35)*	*(TLTHCN36)*	*(TLTHCN37)*
7. K2/Spice:	*(TLK2D1)* ☐	*(TLK2D2)* ☐	*(TLK2D3)* ☐	*(TLK2D4)* ☐	*(TLK2D5)* ☐	*(TLK2D6)* ☐	*(TLK2D7)* ☐
8. Cocaine:	*(TLCOCR1)*	*(TLCOCR2)*	*(TLCOCR3)*	*(TLCOCR4)*	*(TLCOCR5)*	*(TLCOCR6)*	*(TLCOCR7)*

9. Crack:	*(TLCRAKR1)*	*(TLCRAKR2)*	*(TLCRAKR3)*	*(TLCRAKR4)*	*(TLCRAKR5)*	*(TLCRAKR6)*	*(TLCRAKR7)*
10. Amphetamine-type stimulants:	*(TLAMPR1)*	*(TLAMPR2)*	*(TLAMPR3)*	*(TLAMPR4)*	*(TLAMPR5)*	*(TLAMPR6)*	*(TLAMPR7)*
11. Opioid analgesics, including methadone:	*(TLMTDR1)*	*(TLMTDR2)*	*(TLMTDR3)*	*(TLMTDR4)*	*(TLMTDR5)*	*(TLMTDR6)*	*(TLMTDR7)*
12. Heroin:	*(TLHERR1)*	*(TLHERR2)*	*(TLHERR3)*	*(TLHERR4)*	*(TLHERR5)*	*(TLHERR6)*	*(TLHERR7)*
13. Hallucinogens, including MDMA/ecstasy:	*(TLMDAR1)*	*(TLMDAR2)*	*(TLMDAR3)*	*(TLMDAR4)*	*(TLMDAR5)*	*(TLMDAR6)*	*(TLMDAR7)*
14. Sedatives and hypnotics, excluding Benzodiazepines:	*(TLBARR1)*	*(TLBARR2)*	*(TLBARR3)*	*(TLBARR4)*	*(TLBARR5)*	*(TLBARR6)*	*(TLBARR7)*
15. Benzodiazepines:	*(TLBZOR1)*	*(TLBZOR2)*	*(TLBZOR3)*	*(TLBZOR4)*	*(TLBZOR5)*	*(TLBZOR6)*	*(TLBZOR7)*
16. Inhalants:	*(TLINHR1)*	*(TLINHR2)*	*(TLINHR3)*	*(TLINHR4)*	*(TLINHR5)*	*(TLINHR6)*	*(TLINHR7)*
Other Drugs							

17. Other drug 1 use:	*(TLOT1R1)*	*(TLOT1R2)*	*(TLOT1R3)*	*(TLOT1R4)*	*(TLOT1R5)*	*(TLOT1R6)*	*(TLOT1R7)*
Specify other drug 1:	*(TLOTSP11)*	*(TLOTSP12)*	*(TLOTSP13)*	*(TLOTSP14)*	*(TLOTSP15)*	*(TLOTSP16)*	*(TLOTSP17)*
18. Other drug 2 use:	*(TLOT2R1)*	*(TLOT2R2)*	*(TLOT2R3)*	*(TLOT2R4)*	*(TLOT2R5)*	*(TLOT2R6)*	*(TLOT2R7)*
Specify other drug 2:	*(TLOTSP21)*	*(TLOTSP22)*	*(TLOTSP23)*	*(TLOTSP24)*	*(TLOTSP25)*	*(TLOTSP26)*	*(TLOTSP27)*

Comments:*(T53COMM)*

Additional Selection Options for T53

D1 cannabinoids r1
5-05-Ingestion
6-06-Vaporizers
7-07-Spliff
98-98-Other 1
99-99-Other 2

D1 cocaine
5-05-IV Injection
99-99-Other

NIDA Clinical Trials Network

Treatment Status (TSF)

Web Version: 1.0; 1.01; 01-02-14

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment:*(TSFASMDT)* _____ *(mm/dd/yyyy)*

1. Are you currently enrolled in treatment for marijuana dependence?*(PSTHCTRT)* ☐ No ☐ Yes
2. Are you enrolled in maintenance treatment with buprenorphine or methadone? ☐ No ☐ Yes
   (PSBUPTRT)
3. Using the scale below, how would you describe your motivation for decreasing your use of marijuana?

No Desire to Decrease Use									**Greatest Desire to Decrease Use**
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
(PSLOWTHC) ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

4. How many AA, NA, or other self-help groups have you attended in the past 30 days?*(TSSLFHLP)* _____ *(xx)*

Comments:*(TSFCOMM)*

NIDA Clinical Trials Network

Tobacco Use History (TUH)

Web Version: 1.0; 1.02; 01-10-14

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment: *(TUHASMDT)* _____ *(mm/dd/yyyy)*

1. Have you smoked at least 100 cigarettes in your entire life? *(TUSMK100)* ☐ No ☐ Yes ☐ Don't Know/Refused
2. Do you now smoke cigarettes every day, some days, or not at all? *(TUSMFREQ)*
3. Have you EVER smoked cigarettes EVERY DAY for at least 6 months? *(TUEVERY)* ☐ No ☐ Yes ☐ Don't Know/Refused
4. How old were you when you first started smoking cigarettes FAIRLY REGULARLY? *(TUSTRTRG)* _____ *(xx)* Years old

Section A: Every-Day Smokers

5. On the average, about how many cigarettes do you now smoke each day? *(TUNUMDY)* _____ *(xx)* Cigarettes per day

   On average, are the cigarettes you smoke now non-mentholated or mentholated? *(TUTYPEDY)*
6. How old were you when you first started smoking cigarettes every day? *(TUSTRTAG)* _____ *(xx)* Years old

Section B: Some-Day Smokers

7. On how many of the past 30 days did you smoke cigarettes? *(TU30DAYS)* _____ *(xx)* Days
8. On the average, on those [answer to Q7] days, how many cigarettes did you usually smoke each day? *(TU30AVG)* _____ *(xx)* Cigarettes per day
9. In the past 30 days, were the cigarettes you smoked non-mentholated or mentholated? *(TUTYPSDY)*

Section C: Former Smokers

10. When you last smoked every day, on average how many cigarettes did you smoke each day? *(TUNUMEDY)* _____ *(xx)* Cigarettes per day

    On average, were the cigarettes you used to smoke every day non-mentholated or mentholated? *(TUTYPLDY)*
11. When you last smoked fairly regularly, on average how many cigarettes did you smoke each day? *(TUNUMRDY)* _____ *(xx)* Cigarettes per day

    On average, were the cigarettes you used to smoke every day non-mentholated or mentholated? *(TUTYPREG)*

Comments: *(TUHCOMM)*

NIDA Clinical Trials Network

Urine Drug Screen (UDS)

Web Version: 1.0; 4.00; 03-06-14

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

1. Was a urine drug screen performed? *(UDTEST1)* ☐ No ☐ Yes

If "No", reason: *(UDNORSN)*

If "Other", specify: *(UDNOSP1)*

1st Urine Drug Screen

2. Date 1st urine specimen collected: *(UDCOLDT)* _____ *(mm/dd/yyyy)*
3. Was the 1st urine temperature within range? (90 - 100 °F) *(UDTEMP1)* ☐ No ☐ Yes
4. Was the 1st urine specimen determined to be adulterated? *(UDADULT1)* ☐ No ☐ Yes
5. 1st Urine Drug Screen Result(s):

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	*(UDBZO1)* ☐	☐	☐
Amphetamine (AMP):	*(UDAMP1)* ☐	☐	☐
Marijuana (THC):	*(UDTHC1)* ☐	☐	☐
Methamphetamine (MET):	*(UDMET1)* ☐	☐	☐
Opiates (2000 ng) (OPI):	*(UDOPI1)* ☐	☐	☐
Cocaine (COC):	*(UDCOC1)* ☐	☐	☐
Ecstasy (MDMA):	*(UDMDA1)* ☐	☐	☐
Oxycodone (OXY):	*(UDOXY1)* ☐	☐	☐
Methadone (MTD):	*(UDMTD1)* ☐	☐	☐
Barbiturate (BAR):	*(UDBAR1)* ☐	☐	☐

Buprenorphine (BUP): *(UDBUP1)* ☐ Negative ☐ Positive ☐ Invalid

2nd Urine Drug Screen

6. If the 1st urine specimen was determined to be adulterated, was a second specimen collected? *(UDTEST2)* ☐ No ☐ Yes

If "No", reason: *(UDNORSN2)*

If "Other", specify: *(UDNOSP2)*

7. Was the 2nd urine temperature within range? (90 - 100 °F) *(UDTEMP2)* ☐ No ☐ Yes
8. Was the 2nd urine specimen determined to be adulterated? *(UDADULT2)* ☐ No ☐ Yes
9. 2nd Urine Drug Screen Result(s):

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	*(UDBZO2)* ☐	☐	☐
Amphetamine (AMP):	*(UDAMP2)* ☐	☐	☐
Marijuana (THC):	*(UDTHC2)* ☐	☐	☐
Methamphetamine (MET):	*(UDMET2)* ☐	☐	☐

Opiates (2000 ng) (OPI):	*(UDOPI2)* ☐	☐	☐
Cocaine (COC):	*(UDCOC2)* ☐	☐	☐
Ecstasy (MDMA):	*(UDMDA2)* ☐	☐	☐
Oxycodone (OXY):	*(UDOXY2)* ☐	☐	☐
Methadone (MTD):	*(UDMTD2)* ☐	☐	☐
Barbiturate (BAR):	*(UDBAR2)* ☐	☐	☐

Buprenorphine (BUP):*(UDBUP2)* ☐ Negative ☐ Positive ☐ Invalid

Urine Sample Processing and Shipping

10. If the unadulterated sample was negative for Marijuana (THC), was it the 1st time during the course of the trial?*(UDTHCNEG)* ☐ No ☐ Yes

    If "Yes", was the sample processed and shipped to Soft Landing laboratory for synthetic cannabinoid testing?*(UDTHC3)* ☐ No ☐ Yes

    If "No", provide reason:*(UDTHCRSN)* ☐ Study staff error ☐ Other

    If "Other", specify:*(UDTHCSP)*

11. Was the unadulterated sample processed for shipping to the MUSC central laboratory for riboflavin testing?*(UDRIBOFL)* ☐ No ☐ Yes

    If "No", provide reason:*(UDRIBRSN)* ☐ Study staff error ☐ Other

    If "Other", specify:*(UDRIBSP)*

12. Was the unadulterated sample processed for shipping to the MUSC central laboratory for cannabinoids and creatinine testing?*(UDCANNAB)* ☐ No ☐ Yes

    If "No", provide reason:*(UDCABRSN)* ☐ Study staff error ☐ Other

    If "Other", specify:*(UDCABSP)*

Comments:*(UDSCOMM)*

NIDA Clinical Trials Network

Vital Signs (VIS)

Web Version: 1.0; 3.02; 01-09-15

Segment *(PROTSEG)*:
Visit number *(VISNO)*:

Date of assessment:*(VISASMDT)* *(mm/dd/yyyy)*

Body Mass Index

1. Standing height:*(VIHGTIN)* *(xx.x)* inches *(VIHGTCM)* *(xxx)* cm
2. Measured weight:*(VIWTLBS)* *(xxx.x)* lbs *(VIWTKGS)* *(xxx.x)* kgs

BMI:*(VIBMI)*

Vital Signs

3. Heart rate:*(VIPULSE)* *(xxx)* BPM
4. Blood pressure:*(VIBPSYS1)* / *(VIBPDIS1)* Systolic/Diastolic (mmHg)

Comments:*(VISCOMM)*